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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,473	01/29/2001	Michel Philippe	05725.0834	6832
22852	7590	08/03/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005				
		YU, GINA C	ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/770,473	PHILIPPE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Gina C. Yu	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 2/18/2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 31-59 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

Receipt is acknowledged of Amendment filed February 18, 2004. Claims 1-30 are pending. Claim rejection made under 35 U.S.C. § 112, first paragraph, as indicated in the previous Office action dated November 18, 2003, is maintained for the reasons of record and as explained below. Claim rejections made under 35 U.S.C. § 112, second paragraph as indicated in the same Office action are withdrawn in view of applicants' remarks and claim amendment.

Claim rejection made under 35 U.S.C. § 103 (a) over Yu (US 5886041) is withdrawn in view of the new claim limitation. Claim rejection made under 35 U.S.C. § 102 (e) over Thunemann (US 6395284 B1) in view of Aldrich (1996-1997) is withdrawn in view of applicants' remarks. New rejection is made.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph. The specification, while being enabling for the specific skin conditions such as acne, *Propionibacterium granulosum*, hyperseborrhoea as stated in the specification and dependent claims 2, 3, 7, and 8, applicants' disclosure does not reasonably provide enablement for all "disorders associated with seborrhea and disorders associated with microorganisms of the genus *Propiobacterium*" as recited in claim 1.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, because the enablement for the claimed lacks support from the applicant's specification or prior art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

The enablement test requires that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See MPEP § 2164.01, reciting In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). To determine whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue", following factors are considered: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, at 737

In this case, the claim recites the method of treating all disorders associated with seborrhea and the genus *Propiobacterium*, while applicants' specification shows that the present invention is limited to treatment of currently well-known disorders such as seborrhea and acne. It would be unpredictable that the claimed method would be applicable to all disorders that are associated with seborrhea and *Propiobacterium* which may be discovered in the future.

There is no direction provided by applicants for one having ordinary skill in the art to predict that the claimed method would be effective to all skin disorders associated with seborrhea and the microorganism of genus *Propiobacterium*.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In remarks filed February 18, 2004, applicants assert that only two of the above Wands factors were considered by the examiner. Examiner respectfully disagrees. As indicated in the rejection, the ground of the rejection is that applicants' disclosure does not enable the scope of the claimed invention. The breadth of the scope of the invention, which claims the method of treating all disorders associated with seborrhea and the genus *Propiobacterium*, was considered. Examiner also mentioned that specification enables seborrhea and acne only but fails to provide any working example or guidance as to how to make/use the claimed invention with respect to the all claimed skin disorders. Furthermore, examiner respectfully disagrees with applicants' assertion that all of the Wands factors are to be addressed. Examiner views that assessing whether a claimed invention is enabled requires a balancing test of facts available to one of ordinary skill in the art. Nonetheless, examiner asserts that the balancing the facts of the case favors the rejection.

Applicants also argue that the enablement of the present invention is predictable because a vast number of literatures on seborrhea and *Popionibacterium* are available. Applicants' contention that extensive studies

and researches have been conducted on those subject matter has been considered, but the simple number of hits on a data search, even if admitted as a competent evidence, could also mean that the recited skin diseases are too numerous to predict the efficacy of the presently claimed invention. The large number of literatures on these disorders could also mean that the scope of the present claims exceeds the enabled disclosure.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-10, 12-15, 25-27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Thunemann (US 6395284 B1) as evidenced by Aldrich. (1996-1997)

Thunemann teaches the use of poly-L-amino acids such as poly-L-lysine in stabilizing retinoic acid in a composition that is used to treat acne. See example 6. Examiner notes that poly-L-lysine meets the limitation of instant claim 1, formula (I). The reference teaches that poly-L-amino acids are used for the complexation of vitamin A acid. See col. 3, lines 3 – 8. Thunemann fails to teach the molecular weight of poly-L-lysine used in Example 6. The Thunemann composition comprises no other anti-seborreic agent.

Aldrich teaches that poly-L-lysine having average molecular weight in the range of 1K-70K is commercially available. Thus the poly-L-lysine used in Thunemann inherently meets the molecular weight limitation.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-30 have been considered but are not persuasive in part.

Applicants' arguments regarding enablement rejection were addressed above.

In response to applicants argument against rejection made over Thunemman, examiner notes that the presence of vitamin A in the Thunemann composition does not in any way affect the teaching that the use of the polyamino acid compound to treat acne is well known in the art. According to applicants' specification vitamins are not considered an anti-seborrheic agent, and applicants in fact use vitamins as an additive in the composition. The claimed method involves the method of topically applying "at least one compound" chosen from the derivative of polyamino acid of formula (I) and the salts thereof, wherein that selected compound is the only anti-seborrheic agent. Thus the application of the claimed compound along with any other compounds such as vitamin A still meet the claim.

### ***Conclusion***

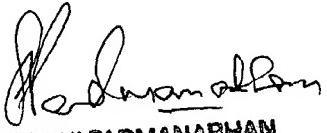
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-

272-0635. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER